IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

ROBERT BLANCO, Plaintiff, v. WYETH, INC., f/k/a American Home Products Corporation, WYETH PHARMACEUTICALS, INC., f/k/a Wyeth-Ayerst Pharmaceuticals, Inc., f/k/a Wyeth Laboratories, Inc. Defendants.	)	Civ. Action No.: 3:10-cv-0033-JRS

WYETH'S MEMORANDUM IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE THE TESTIMONY OF DR. CHERYL BLUME

Defendants Wyeth LLC (incorrectly identified in Plaintiff's Complaint as Wyeth Inc., f/k/a American Home Products Corporation) and Wyeth Pharmaceuticals Inc. (incorrectly identified in Plaintiff's Complaint as Wyeth Pharmaceuticals, Inc., f/k/a Wyeth-Ayerst Pharmaceuticals, Inc., f/k/a Wyeth Laboratories, Inc.) (collectively, "Wyeth"), by counsel, state as follows in support of their Motion *In Limine* to Exclude the Testimony of plaintiff's expert Dr. Cheryl Blume:

PRELIMINARY STATEMENT

Dr. Blume is a pharmacologist by training who is expected to testify that Wyeth's medications, Pondimin and Redux™, can cause primary pulmonary hypertension ("PPH").[1] She offers no opinions about Mr. Blanco in particular. Although Wyeth has no objection to Dr. Blume giving general causation testimony within the scope of her expertise—pharmacology—

[1] Plaintiff alleges that he ingested Redux™ only, therefore testimony regarding Pondimin is irrelevant. Notwithstanding this, Wyeth will not contest at trial that Pondimin and Redux™ can cause PPH in a very small percentage of people in some circumstances. Thus, such testimony from

Wyeth would object to cumulative testimony on such matters from the multiple experts Plaintiff has designated. Dr. Blume also should not be permitted to testify about: (1) the relative risks and benefits of Pondimin and Redux™, or (2) Wyeth's alleged knowledge and intent in how it labeled and marketed Pondimin and Redux™. Both topics are beyond the scope of Dr. Blume's expertise, and the second is an improper subject for expert testimony, in any event.

ARGUMENT

I. Standards for Admissibility of Expert Testimony.

A federal district court judge must play "a gatekeeping role" when considering the admissibility of expert testimony or evidence. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 597 (1993). Because expert witnesses, unlike lay witnesses, may offer opinions that are not based on first-hand knowledge or perceptions, *compare* Fed. R. Evid. 702 *with* Fed. R. Evid. 701, and because "expert evidence can be both powerful and quite misleading," *Daubert*, 509 U.S. at 595, district courts must determine the admissibility of expert testimony as a preliminary matter under Federal Rule of Evidence 104(a). *See id.* at 592; *Cavallo v. Star Enterprise*, 892 F. Supp. 756, 761 (E.D. Va. 1995) (Ellis, J.), *aff'd in part rev'd in part sub. nom.*, 100 F.3d 1150 (4th Cir. 1996). Federal Rule of Evidence 702 is "the primary locus," *Daubert*, 509 U.S. at 589, 125 L. Ed. 2d at 482, of a district court's discharge of its "gatekeeping responsibility." *Id.* at 480 n.7. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill,

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Dr. Blume is unnecessary.

> experience, training, or education may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

The *Daubert* Court identified two critical components to Rule 702. First, to be admissible, an expert's testimony must be scientific knowledge. This requirement "establishes a standard of evidentiary reliability," or "trustworthiness," *Daubert*, 509 U.S. at 589-90 and n.9, in the sense of "scientific validity." *Cavallo*, 892 F. Supp. at 761. To qualify as scientific, an expert's testimony must be "ground[ed] in the methods and procedures of science." *Daubert*, 509 U.S. at 590; *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir.), *cert. denied*, --- U.S. ---, 132 L. Ed. 2d 871 (1995); *Cavallo*, 892 F. Supp. at 760-61. To be considered knowledge, it must "connote[] *more than subjective belief or unsupported speculation*." *Daubert*, 509 U.S. at 594 (emphasis added); *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.") (emphasis in original); *Cavallo*, 892 F. Supp. at 761. In *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001), the court reaffirmed that the purpose behind *Daubert*'s focus on reliability is to "make certain that an expert … employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

The second critical component to Rule 702 is the requirement that expert testimony assist the trier of fact. This condition to admissibility amounts to a special rule of relevance regarding expert testimony. *See Daubert*, 509 U.S. at 591; *Cavallo*, 892 F. Supp. at 760. To be admissible, an expert's testimony must have "a valid scientific connection to the pertinent inquiry…." *Daubert*, 509 U.S. at 592-93. In short, the scientific validity of the expert's

testimony must "fit" the purpose for which it is used, because "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes." *Id.* at 591; *Cavallo*, 892 F. Supp. at 761.

As this Court has stated, "[t]he distinction between 'scientific validity' and 'fit' is not always clear, and the two inquiries may overlap in a particular case." *Cavallo*, 892 F. Supp. at 761. Thus,

> [a]lthough courts must not exclude expert testimony based on a valid methodology simply because they disagree with the ultimate conclusion reached, they ***have an obligation to ensure that the conclusion is reliable***, that is, that there is a ***scientifically valid link*** between the sources or studies consulted and the conclusion reached.

Cavallo, 892 F. Supp. at 762 (emphasis added). The Supreme Court reaffirmed these principles in *General Electric Co. v. Joiner*, 118 S. Ct. 512, 517 (1997), in which it observed:

> [C]onclusions and methodologies are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert.

Joiner, 118 S. Ct. at 519.

In *Kumho Tire Co. v. Carmichael*, 119 S. Ct. 1167 (1999), the Supreme Court reiterated the importance of *Daubert*'s gatekeeping requirement. Although the Court recognized in that case that a trial court has "considerable leeway" in analyzing disputed expert testimony, *see Kumho Tire*, 119 S. Ct. at 1176, "discretion in choosing the manner of testing expert reliability is not discretion to abandon the gatekeeping function … [or] discretion to perform the function inadequately." *Id.* at 1179 (Scalia, J., concurring). Indeed, as the author of the *Kumho Tire* opinion noted in *Joiner*: "[N]either the difficulty of the task nor any comparative lack of

expertise can excuse the judge from exercising the 'gatekeeper' duties that the Federal Rules of Evidence impose – determining, for example, whether particular expert testimony is reliable and 'will assist the trier of fact.'" *Joiner*, 522 U.S. at 148 (Breyer, J. concurring). A Virginia federal court has interpreted the mandate from *Kumho Tire* as follows:

> While there are certainly times when, given the complexity of issues or the ferocity of the debate, it may seem expedient just to let opposing experts do battle at trial, the Supreme Court has made clear that to do so, without due circumspection, would be shirking my duty as evidentiary 'gatekeeper' to the trial process.

Hartwell v. Danek Medical Inc., 47 F. Supp. 2d 703, 711 (W.D. Va. 1999).

The burden of establishing the reliability and relevance of expert testimony is on the proponent of such testimony. *Perkins v. United States of America*, 626 F. Supp. 2d 587, 592 (E.D. Va. 2009); *accord Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). This Court should conduct an evidentiary hearing to determine Dr. Blume's qualifications and the reliability and relevance of her opinions. *See* Fed. R. Evid. 104(a); *Daubert*, 509 U.S. at 592. Accordingly, Wyeth hereby requests such a hearing before Dr. Blume is permitted to testify at trial.

II. Dr. Blume Is Not Qualified To Offer Opinions Regarding The Relative Risks And Benefits Of Pondimin or Redux

With the applicable legal standards in mind, it is apparent that Dr. Blume lacks the qualifications to provide evidence regarding many of the issues that Plaintiff is expected to attempt to offer from this witness.

If the Court does not exclude Dr. Blume's testimony as cumulative of the other two Plaintiff's experts who opine on the same topics, as discussed below in section IV, at minimum her testimony should be limited to topics within her true field of expertise. In particular, Dr. Blume's report includes opinions on whether the benefits associated with diet

drugs, including Pondimin and Redux, are outweighed by the risks to patients, although she lacks the training and experience to offer any reliable and relevant opinion about this relationship. *See* Expert Report of Dr. Cheryl Blume, hereinafter "Blume Report" (attached as **Exhibit A**)[2]. Dr. Blume is a Ph.D. pharmacologist -- not a medical doctor -- who provides "generic" opinions, *i.e.*, opinions not specifically related to plaintiffs, for plaintiffs in diet drug cases. She has been involved in the development of certain drugs, but not in the development or study of diet drugs of any kind. Dr. Blume has degrees in "biology and medical pharmacology"[3] and consults as an "expert witness in clinical pharmacology, toxicology and in pharmaceutical related litigation." *See* Blume Curriculum Vitae (attached as **Exhibit B**). A significant portion of her pharmacology experience has been in *laboratory* studies "spearheading" product development and invention. *Id.* This apparently refers to early stage research on potential pharmaceutical products. She is not a medical doctor and, therefore, cannot treat patients or prescribe drugs. *Id.* Because she has never treated a patient, or had to prescribe a drug, she has never had to decide whether the benefits of a drug outweigh the risks for any one person or whether the drug should be prescribed to an individual. *Id.*

There is no evidence that she has ever reviewed any medical literature relating to diet drugs and their alleged association with PPH prior to her involvement in diet drug litigation. *Id.* Rather, she has apparently reviewed only information selected and provided to her by various plaintiffs' counsel, which largely includes materials from prior diet drug trials. *Id.* Nothing in her report or curriculum vitae indicates that she has made any effort to review and

[2] By letter dated May 30, 2008, Plaintiff designated Cheryl Blume as a general expert witness in this case and submitted by agreement, the expert report of Ms. Blume in another diet drug case, *Gloria Stribling v. American Home Product*.

[3] Pharmacology is the study of drugs including their origin, composition, pharmacokinetics (the body's reaction to drugs), therapeutic use, and toxicology.

analyze the literature about the relative risks of obesity and Redux, the drug ingested by Plaintifff.[4]

Dr. Blume also has no expertise -- that is, no training, education, or experience — concerning the efficacy of weight loss medications in general or of Redux (or the related medication, Pondimin) in particular. Dr. Blume has not been involved in any research involving anti-obesity drugs. Nor is there any evidence that she has conducted any research into the efficacy of Reduxas a weight loss medication. Thus, she has no reliable basis for any opinion that the benefits of Reduxwere outweighed by the risks.

The MDL Court supervising discovery in these diet drug cases has previously held that purported "experts" on obesity who, like Dr. Blume, had insufficient experience "treating or studying obesity" could *not* opine on the efficacy of Pondimin or Redux™ in inducing weight loss. *See In re Diet Drugs* (*Phentermine, Fenflurarnine, Dexfenfluramine*) *Prods. Liab. Litig.*, MDL No. 1203, Pretrial Order 1685, 2001 WI. 454586 (E.D. Pa. Feb. 1, 2001), at *21 (attached as **Exhibit C**). In so holding, the MDL Court stated that even "general training and experience as *physicians* in evaluating the risks and benefits of drugs does not translate into the specific expertise to render expert opinions about the efficacy of a specific class of drugs such as those at issue here." *Id.* (emphasis added). Thus, even if Dr. Blume were able to establish that she has some training or experience in evaluating the risks and benefits of drugs — which she does not — such a showing still would be insufficient to qualify her to render opinions as to the efficacy of Pondimin and Redux™.

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[4] Because Dr. Blume's opinions are based on her review of materials selected by plaintiff's counsel for the purpose of litigation, they are inherently suspect. *See Nelson v. American Home Products Corp.*, 92 F. Supp. 2d 954, 967 (W.D. Mo. 2000) ("[I]n determining the reliability of a proffered expert's opinion, courts have discounted the reliability of experts who formed their opinions only within the context of litigation."); *National Bank of Commerce (of El Dorado, Ark.) v. Dow Chemical Co.*, 965 F. Supp. 1490, 1516-17 (E.D. Ark. 1996) (finding expert unreliable after noting that her testimony was tainted by "litigation animus"), *affd*, 133 F.3d 1132 (8th Cir. 1998).

In its role as "gatekeeper," the Court is required to enforce boundaries between areas within which an expert is qualified and those in which she is not. *See, e.g.,* Fed. R. Evid. 702; *Hartwell*, 47 F. Supp. 2d at 715 (expertise in one area does not qualify expert in fields where there is no expertise); *Roche v. Lincoln Prop. Co.*, 278 F. Supp. 2d 744, 754, 755 (E.D. Va. 2003) (physician in toxic mold case was not qualified to render a causation opinion because he did not have expertise in specific fields of toxicology, microbiology, or industrial hygiene); *Scott v. Mid-Atlantic Cable Installation, LLC*, No. 1:05 cv 970, 2006 U.S. Dist. LEXIS 50767, *8 (E.D. Va. 2006) (excluding portion of expert's opinion related to ergonomics when the expert's training in ergonomics was "minimal"). In this case, Dr. Blume does not have a sufficient basis for opining on issues of the relative risks and benefits of Redux, and therefore, her opinions on those topics should be excluded.

III. Dr. Blume Cannot Offer An Expert Opinion On Wyeth's Intent or Alleged Violations of FDA Regulations

In Dr. Blume's expert report, she opines on how a "prudent pharmaceutical company" would have acted and, in particular, purports to describe Wyeth's knowledge and intent concerning the labeling, marketing, and sale of Pondimin and Redux. *See* Ex. A, Blume Report, at 1042. For instance, she claims that "examples of Wyeth's inappropriate and dangerous tactics also include such notable actions as hiring lobbyists and consultants masquerading as objective scientists *for the purpose of* exaggerating the health benefits while minimizing the health risks of Redux and Pondimin." *See id.*, at 79 (emphasis added). She further opines that "[a]ll of this was apparently done *with the knowledge and consent of Wyeth." See id.* at 80 (emphasis added). This is improper expert testimony because it relates to a subject in which Dr. Blume has no particular expertise or knowledge, and further, it will not assist the trier of fact but, rather, will usurp the function of the trier of fact.

Federal Rule of Evidence 702 provides that expert testimony is permissible only when "scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." Fed. R. Evid. 702. Jurors can independently and adequately interpret evidence regarding what Wyeth allegedly knew and when, and regarding what Wyeth's "purpose" was. Such matters are within jurors' common experience and knowledge and are an improper subject for expert testimony of any sort, much less speculation by Dr. Blume. Her idiosyncratic and unscientific characterizations of Wyeth's conduct and subjective intent demonstrate no "scientific, technical or other specialized knowledge," are not based on any accepted methodology, and are unfairly prejudicial because they dress a tainted picture of Wyeth in the garb of "expertise." Fed. R. Evid. 702, 403 (relevant evidence may be excluded where "its probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues, or misleading the jury or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."); *United States v. Lester*, 254 F. Supp. 2d 602, 607 (E.D. Va. 2003) (because "[e]xpert evidence can be both powerful and quite misleading," *Daubert*, 509 U.S. at 595, the court "exercises more control over experts than over lay witnesses" and has a "continuing obligation under Rule 403 to exclude [expert] evidence, the probative value of which is substantially outweighed by the danger of confusi[on]."); *see also Virginia Vermiculite, Ltd. v. W. R. Grace & Co.-Conn.*, 98 F. Supp. 2d 729, 735 (W.D. Va. 2000) ("Expert testimony with a greater potential to mislead than to aid . . . should be excluded.").

In fact, the federal district court overseeing the diet drug MDL has excluded just this type of testimony from other plaintiffs' experts in the diet drug litigation. *See, e.g., In re diet drugs (Phentermine, Fenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at

*9 (E.D. Pa. June 20, 2000) (precluding two witnesses from testifying about Wyeth's corporate intent, stating that "[t]he question of intent is a classic jury question and not one for experts, and clearly not these experts") (citations omitted) (attached as **Exhibit D**); *see also* Ex. B, *In re Diet Drugs* Order, at *24 (E.D. Pa Feb. 1, 2001) (granting Wyeth's motion to exclude testimony offered by five plaintiffs' experts "as to the intent of [Wyeth] and/or beliefs of FDA officials as evidence by the words or conduct of their agents, servants or employees"). Dr. Blume's personal and subjective value judgments on Wyeth should be excluded for the same reason. In addition, to the extent this testimony is intended to show "bad character" on the part of Wyeth, the rules of evidence prohibit its admission. *See* Fed. R. Evid 404.

Finally, to the extent that she purports to do so in her expert report, Dr. Blume lacks the experience and training to opine on Wyeth's compliance with FDA regulations and standards. *See generally*, Ex. A, Blume Report. Also, Dr. Blume's opinions on what the FDA regulations mean involve questions of law to be resolved by the judge, not by an expert.[5] As such, such opinions should be excluded.

IV. The Court Should Exclude Testimony From Dr. Blume That Is Cumulative And Will Cause Delay And Confusion

A principal topic on which Dr. Blume will purportedly opine is that epidemiologic evidence shows that diet drugs —Reduxin particular — cause primary pulmonary hypertension ("PPH"). *See* Ex. A, Blume Report, at 22 ("In summary, anorexic agents such as Aminorex,

[5] *See also,* e.g. *Bammerlin v. Navistar Intl Transp. Corp.*, 30 F.3d 898, 900 (7th Cir. 1994)("The meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts. It is a question of law, to be resolved by the court"); *Frase v. Henry,* 444 F.2d 1228, 1231 (10th Cir. 1971) ("Moreover, it is clearly not the function of an expert to state unadorned legal conclusions . ."); *United States v. Weitzenhoff*, 35 F.3d 1275, 1287 (9th Cir. 1993) ("The court's admission of expert testimony on contested issues of law in lieu of instructing the jury was

Pondimin, or Redux may precipitate PPH through two distinct actions . . .”). At least two other experts designated by Plaintiff have submitted reports making precisely the same assertion. *See, e.g.*, Expert Report of Dr. Lemuel Moye, at 1 ("To a reasonable degree of scientific and medical certainty, the fenfluramines cause primary pulmonary hypertension") (attached as **Exhibit E**); Expert Report of Dr. Laura Plunkett Report, at ¶ 10 ("Specifically, use of [Pondimin and Redux™] has been causally associated with primary pulmonary hypertension . . .") (attached as **Exhibit F**). Plaintiff should not be permitted to offer testimony on precisely the same topic from Dr. Blume as well as from Drs. Moye and Plunkett.

District courts regularly exclude expert opinion testimony that amounts to the same opinions as another expert as well as testimony that is predicated on the same evidence as the opinions of other experts. *See Cabrea v. Cordis Corp.*, 134 F.3d 1418, 1421-23 (9th Cir. 1998) (excluding as "needless presentation of cumulative evidence" testimony of second expert offering same opinions as existing evidence in case); *American Nat. Fire Ins. Co. v. Mirasco, Inc.*, 265 F. Supp. 2d 240, 254 (S.D.N.Y. 2003) (excluding as "cumulative" and "superfluous" the testimony of second expert offering same opinions of another expert with "greater experience" on the issue); *Colon v. Bic, USA, Inc.*, 199 F. Supp. 2d 53, 96-97 (S.D.N.Y. 2001) (holding that expert testimony predicated upon same evidence as testimony of other experts is "cumulative" and should be excluded). The jury does not need to hear the same information from three different experts, particularly three different generic experts who have not even treated Plaintiff. Permitting Dr. Blume's cumulative testimony on this issue would thus add unnecessary confusion and delay to what will already be a complex and lengthy trial. *See* Fed. R. Evid. 403; *United States v. Morison*, 844 F.2d 1057, 1080 (4th Cir.), cert. denied, 488 U.S. 908 (1988). Accordingly, Dr.

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manifestly erroneous.")

Blume's opinion testimony is cumulative, will cause delay and confusion, and should be excluded from the trial of this matter.

CONCLUSION

For the reasons stated above, Wyeth respectfully requests an order precluding Plaintiff from introducing cumulative expert testimony from Dr. Blume and precluding Plaintiff from introducing any testimony from Dr. Blume regarding the issues outlined above that are outside her area of expertise, irrelevant, and/or improper subjects for expert testimony. In the alternative, Wyeth respectfully requests that the Court conduct a preliminary hearing pursuant to Federal Rule of Evidence 104.

WYETH, INC., and
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I hereby certify that on this 15th day of July, 2010, a true copy of the foregoing will be filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following:

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